ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301B "Ready Biodegradability: Modified Sturm Test."
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1991
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	Inoculum: Activated sludge microorganisms were obtained from a municipal sewage treatment plant at Wateschap de Aa, Schijndel, the Netherlands. Concentration of test chemical: The test material was used at concentrations of 10 and 20 mg/L. Test Setup: Nutrient medium was prepared by adding 2 mL of a potassium phosphate solution, 1 mL each of magnesium sulfate, calcium chloride, and ammonium sulfate solutions, and 4 mL of a ferric chloride solution to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with the nutrient culture medium and 30 mL of inoculum and aerated over night. On day 1 of the study, the test and reference material (sodium benzoate, 20 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO_2 absorption bottles were connected in series to the exit air line of each bottle. CO_2-free air was bubbled through the solution. All experiments were performed at 20 to 22°C. Sampling frequency: Samples were collected from the first CO_2 absorber vessel on days 2, 5, 7, 9, 12, 16, 21, and 28. Controls: Yes. Analysis: Samples from the CO_2 absorbers were analyzed using a Heraeus CHN-analyzer.

Results	
Degradation % after time	6.6% at 10 mg/L and 6.3% at 20 mg/L at 28 days (test article); 71% at 28 days (sodium benzoate).
Conclusions	The test article, at low and high concentrations, was degraded approximately 6% after 28 days and sodium benzoate was degraded 71% after 28 days. Under the conditions of the OECD guidelines, the test article was not readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Coenen, T.M.M. 1991. Ready biodegradability: modified Sturm test. RCC NOTOX Project 052559. NOTOX, The Netherlands.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1986
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	5,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>5,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral dose of 5000 mg/kg of dimer (CAS #61788-89-4) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. No effects on mortality, clinical signs or body weight were reported. Gross necropsy revealed no treatment-related effects. The acute oral LD_{50} was greater than 5000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Thouin, M.H. 1986. Evaluation of acute oral toxicity of [trade name deleted; dimer] in the rat. NOTOX 0336/416. NOTOX, The Netherlands.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1989
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	2,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>2,000 mg/kg
Detailed Summary	Sprague-Dawley rats (n = 5/sex) received a single oral dose of 2000 mg/kg of dimer (CAS #61788-89-4) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. No mortalities occurred and no changes in clinical signs, body weight or gross pathology were reported. The acute oral LD_{50} was greater than 2000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Saboureau, D. 1989. Evaluation of the acute toxicity in the rat by the oral route. TAO 88.1518. Biogir S.A. Conseil Recherche, France.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers, hydrogenated
CAS #	68783-41-5
Remarks	This substance is referred to as hydrogenated dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1988
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	5,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>5,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral dose of 5000 mg/kg of hydrogenated dimer (CAS #68783-41-5) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. Mortality, clinical signs, body weight, and gross pathology were unaffected by treatment. The acute oral LD_{50} was greater than 5000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Reijnders, J.B.J. 1988. Acute oral toxicity of [trade name deleted; hydrogenated dimers] in the rat. RCC NOTOX 0811/1041. NOTOX, The Netherlands.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 408, "Subchronic Oral Toxicity – Rodent: 90-Day."
Year	1993
GLP (Y/N)	Y
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	13 weeks
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.1, 1, 5%
Control group (Y/N)	Y
Results	
NOAEL:	0.1%
Detailed Summary	Dimer (CAS #61788-89-4) was administered to CD Sprague-Dawley rats (n = 20/sex/group) in the diet at concentrations of 0, 0.1, 1, or 5% for 13 weeks. The approximate doses were 0, 100, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included clinical signs, body weight, food and water consumption, ophthalmoscopy, hematology, clinical chemistry, gross pathology, organ weights (brain, heart, liver, kidneys, spleen, testes, adrenal glands), and microscopic pathology (adrenal glands, brain, colon, femur and stifle joint, ileum, larynx, lymph nodes, muscle, ovaries and fallopian tubes, pituitary, sciatic nerve, sternum, thyroid and parathyroids, uterus, aorta, cecum, duodenum, head, jejunum, liver, esophagus, pancreas, prostate, spinal cord, stomach, tongue, bladder, cervix, heart, kidneys, lungs, mammary glands, rectum, spleen, thumus, trachea, epididymides, skin, salivary glands, testes, seminal vesicles, vagina, eyes/harderian glands). No deaths occurred and no treatment-related effects on clinical signs, body weight, body weight gain, water intake, or ophthalmoscopy were noted. A transient, statistically significantly decrease in food consumption occurred in the 5% males and females during the first four weeks of study. The animals exhibited normal consumption from week 4 through 13. Slight changes in hemoglobin (increased in 5%

	males) and prothrombin time (increased in 1% females and 5% males and females) were considered not to be toxicologically significant. Treatment-related clinical chemistry changes included statistically significant increases in alkaline phosphatase (1 and 5% males and females) and ALT (5% males and females), and statistically significant decreases in total cholesterol (1 and 5% males and females), triglycerides (1% males and 5% males and females), total serum protein and albumin (5% males and females), and beta-globulin fraction (1 and 5% males). At necropsy, the mesenteric lymph nodes were slightly to moderately enlarged in all dimer treatment groups and the incidence of uterine fluid distension was increased at 5%. Absolute and relative spleen (males at 1 and 5%) and liver (males and/or females at 1 and 5%) weights were statistically significantly decreased. In addition, absolute kidney weight was significantly decreased in females at 5% and absolute and relative liver weights were significantly decreased in females at 0.1%. The relevance of these decreases in organ weights is not known, since they did not correlate to any microscopic changes. Histopathology revealed treatment-related findings in the following organs: mesenteric lymph nodes (aggregation of macrophages in both sexes at 0.1% and higher); spleen (macrophages with brown pigment in both sexes at 1 and 5% and in the females at 0.1%); liver (bile duct proliferation and bile duct sclerosis in males at 5%); adrenals (cortical vacuolation in females at 1 and 5%); and thyroids (follicular epithelial hypertrophy in females at 5%). Although a no-effect-level was not identified in this study, 0.1% (approximately 100 mg/kg/day) can be considered a no-observed-adverse-effect-level based on increases in clinical chemistry parameters and histopathological findings at the higher doses.
Data Quality	Valid without restriction – Klimisch Code 1a
References	Spurgeon, M., and Hepburn, P. 1993. Dimer acid: 13 week feed study in the rats. Study FT920485. Environmental Safety Laboratory, England. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD method # 471, "Bacterial Reverse Mutation Assay"
Year	2000
GLP (Y/N)	Yes
System of testing	*S. typhimurium* strains TA98, TA100, TA 102, TA1535, TA1537
Concentrations	33, 100, 333, 1000, 2500 and 5000 µg/plate
Metabolic activation	With and without S9
Results	Non-mutagenic
Detailed Summary	An Ames test was conducted in *S. typhimurium* strains TA98, TA100, TA 102, TA1535, and TA1537. Dimer (CAS #61788-89-4) concentrations of 33, 100, 333, 1000, 2500 and 5000 µg/plate were tested with and without metabolic activation (S9 mix). No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with dimer at any concentration level either in the presence or absence of metabolic activation (S9 mix). Thus, dimer was not considered to be mutagenic.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Wollny, H. 2000. Salmonella Typhimurium assay with [trade name deleted; dimers] RCC Cytotest Cell Research, GMBH, Robdorf.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 476, "*In vitro* Mammalian Cell Gene Test."
Year	1993
GLP (Y/N)	Y
System of testing	Mouse lymphoma L5178Y cells
Concentration	25 to 300 µg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Dimer (CAS #61788-89-4) was incubated *in vitro* with L5178Y mouse lymphoma cells for three hours at concentrations ranging from 25 to 300 µg/mL with and without metabolic activation (S9 mix). Samples were collected at 24 and 48 hours to assess growth. After 48 hours, cells were collected, plated, and incubated for 12 days to assess viability and mutant frequency. The assay was conducted in duplicate. In Test 1 (without S9), toxicity was observed at 300 µg/mL and in Test 2 (without S9) toxicity was observed at 275 and 300 µg/mL. These concentrations were excluded from the mutation analyses. A statistically significant increase in mutant frequency was observed in Test 2 at 250 µg/mL. However, because the increase was small, it was not considered biologically significant; no increase occurred in Test 1. Tests 1 and 2 (with S9 mix) produced reduced survival at 300 µg/mL and 250 µg/mL and above, respectively. These concentrations were excluded from the mutation analyses. No increase in mutant frequency was observed. Dimer acid did not demonstrate mutagenic potential in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Adams, K. 1993. Dimer acid: mouse lymphoma TK locus assay. ULR 472/930202. Huntingdon Research Centre Ltd., England.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the test plan for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 473, "*In Vitro* Mammalian Cytogenetic Test."
Year	1993
GLP (Y/N)	Y
System of testing	Human lymphocytes
Concentration	9.4 to 300 µg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Human lymphocytes were incubated with dimer (CAS #61788-89-4) at concentrations ranging from 75 to 300 µg/mL with and without metabolic activation. In the first assay, the cultures containing S9 mix were centrifuged three hours after dosing and fresh medium was added for an additional 15 hours. In the second assay, half the cultures were processed following the procedure used in the first assay with a harvest at 18 hours and the other half were harvested at 32 hours. For all tests, two hours prior to treatment cessation, mitotic activity was arrested by the addition of colchicine, and the number of mitotic cells per 1000 cells in each culture was determined microscopically. No significant increase in the proportion of aberrant cells was observed in either the first or second assay with or without metabolic activation. Dimer demonstrated no clastogenic activity in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Akhurst, L. 1993. Dimer acid: metaphase chromosome analysis of human lymphocytes cultured *in vitro*. ULR 471/930241. Huntingdon Research Centre Ltd., England.